

Appl. No. 09/714,040
Amendment dated March 19, 2004
Reply to Office Action of May 20, 2003

REMARKS

Applicants request entry of this Amendment and reconsideration of the rejection of the claims. Applicants have cancelled claims 30-37 without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of these claims in one or more continuation applications.

Information Disclosure Statement

Applicants submitted an Information Disclosure Statement on November 15, 2000. Applicants have not received the initialed copy of the PTO 1449 that was submitted on that date. Applicants request consideration of the references and return of the initialed 1449. A courtesy copy of the 1449 as submitted on November 15, 2004 is enclosed. The documents listed on the form were provided in parent application Serial No. 08/199,268, filed February 28, 1994.

35 U.S.C. § 112, Second Paragraph

Applicants acknowledge withdrawal of the rejection of claim 25 on this basis.

35 U.S.C. § 112, First Paragraph

The Examiner has rejected claim 25 under 35 U.S.C. § 112, first paragraph, because the Examiner contends the specification does not enable how to make the invention. The Examiner asserts that the specification does not enable a $F(ab')_2$ homogenous as to heavy chain C-terminal amino acid residue, because the specification teaches Cys Ala Ala as the only one product that is homogenous to the heavy chain C-terminal residue. Applicants respectfully traverse.

Applicants contend that one of skill in the art reading the specification would be able to make a $F(ab')_2$ as claimed without undue experimentation. There are many factors to be considered in an analysis of enablement including breadth of claims, nature of the invention, the state of the prior art, the level of ordinary skill, level of predictability in art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation. MPEP 2164.01(a) citing In Re Wands, 858 F2d 731, 737 (Fed. Cir. 1988). Only a reasonable correlation between enablement and the scope of the claims is required.

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Applicants submit one of skill in the art reading the specification would be able to make a $F(ab')_2$ as claimed. Applicants have described at least one method for obtaining the $F(ab')_2$ in the specification including a working example. The specification at page 14, line 7, to page 16, line 3, describes a vector for producing $F(ab')$, methods for isolation of $F(ab')$ or $F(ab')_2$, and methods for producing $F(ab')_2$ by chemical coupling. In addition, Applicants have provided detailed description starting at page 21, line 25, concerning vectors, vector components, host cells, and purification conditions. In the Examples and Figures 1 and 2, Applicants provide a working example describing in detail the vector construction, expression and purification scheme for a $F(ab')$ or for $F(ab')\text{-TNB}$ and a method for forming and isolating $F(ab')_2$. Thus, Applicants submit one of skill in the art could readily substitute other antibody fragment sequences in the method as described in the specification and prepare a $F(ab')_2$ as claimed without undue experimentation.

The Examiner contends that Applicants have only provided a single example of a product that is homogenous at the C-terminal. However, the Examiner has presented no technical reasons why other antibody fragment sequences could not be utilized in the methods of the invention to form a $F(ab')_2$ without undue experimentation. Therefore, Applicants respectfully request withdrawal of the rejection on this basis.

Request for an Interview

Applicants request an interview with the Examiner and his or her supervisor upon receipt of these papers.

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SUMMARY

Applicants submit the claims are in condition for allowance and request notification to that effect.

Respectfully submitted,

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